

Focus Report
New Chemicals Program
PMN Number: **L-14-0050**

Focus Date: 12/09/2013 12:00:00 AM Report Status: Completed
Consolidated Set:
Focus Chair: Loraine Passe Contractor: Olga Svetlitskaya

I. Notice Information

Submitter: Resman USA CAS Number: [REDACTED]
Chemical Name: [REDACTED]

Use: Chemical tracer for production monitoring in oil and gas wells. [REDACTED]

Other Uses: [REDACTED]

PV-Max: 10,000 Kg/yr Binding Option: No
Manufacture: Import: X

II. SAT Results

(1) **Health Rating:** 1-2 **Eco Rating:** 2 **Comments:** ;

Occupational: 1C **Non-Occupational:** 1 **Environmental:** 1

(1) **PBT:** 3 1 1 **Comments:**
Awaiting Human
Health Entry
Awaiting Human
Health Entry
Awaiting Human
Health Entry

III. OTHER FACTORS

Categories:

Health Chemical Category: Ecotox SAR and nonionic surfactants; Nonionic
TSCA New Surfactants
Chemical
Category:

Related Cases/Regulatory History:

Health related Cases:
Ecotox Related Cases:
Regulatory History:

[REDACTED]

MSDS/Label Information:

MSDS: Yes Label: No
General Equipment: gloves (selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it) / Safety glasses with side-shields conforming to EN166. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN166 (EU). / Impervious clothing.
Respirator: For nuisance exposures use type P95 (US) or type P1 (EU EN 143) particle respirator. For higher level protection use type OV/AG/P99 (US) or type ABEKP2 (EU EN 143) respirator cartridges. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
Health Effects: Inhalation of dust from the break down products may however cause headaches or respiratory irritation. Prolonged or repeated exposure can irritate eyes and skin.

TLV/PEL (PMN or raw material): - none established.
LVEPPE: Solid form, PPE: gloves, eye protection

Exposure Based Information:

Exposure Based Review: N
Exposure Based Review (Eco): N
Exposure Based Review (Non Occupational):

Exposure Based Review (Health): N
Exposure Based (Occupational): No
Exposure Based (Environmental):

IV. Summary of SAT Assessment

Fate:

Fate Summary:

L-14-0049-50
FATE: Estimations for typical MW 651
Liquid with MP < 25 C (E)
log Kow = 3.64 (E)
S = 9.31 mg/L at 25 C (E)
VP < 1.0E-6 torr at 25 C (E)
BP > 400 C (E)
H < 1.00E-8 (E)
log Koc = 6.69 (E)
log Fish BCF = 2.07 (E)
log Fish BAF = 2.27 (E)
POTW removal (%) = 0-25 via sorption;
. L-14-0050: OECD 306(Biodeg in Seawater, Closed Btl): <4%/28d.
Time for complete ultimate aerobic biodeg > mo
Sorption to soils/sediments = moderate
PBT Potential: P3B1
*CEB FATE: Migration to ground water = moderate

Health:

Health Summary:

Absorption of the low molecular weight fraction (100% < 1000, 0% < 500) is poor all routes, based on physical/chemical properties. There are concerns for solvent irritation to the eye, skin, and mucous membranes and for solvent neurotoxicity.

Ecotox:

Ecotox Values:

Fish 96-h LC50:	1.3(P)	
Daphnid 48-h LC50:	0.23(P)	1.8(M)
Green algal 96-h EC50:	0.29(P)	
Fish Chronic Value:	0.26(P)	
Daphnid ChV:	0.046(P)	0.36(M)
Algal ChV:	0.22(P)	

Ecotox values comments: Predictions are based on SARs for nonionic surfactants; SAR chemical class = surfactant-nonionic; MW 732 with 100% < 1000 and 0% < 500; S = 0.12 mg/L @ 20 C (P); liquid with unknown mp (P); pH7; effective concentrations based on 100% active ingredients and mean measured concentrations; DW hardness <150.0 mg/L as CaCO3; and DW TOC <2.0 mg/L;

Ecotoxicity Test Data Results: L-14-0050;

Fish Ecotoxicity Test:

Environmental Enterprises USA, Inc. conducted a 7-day larval survival and growth test in the inland silverside (*Menidia beryllina*) with L-14-0050 (purity= 93.4%) under semi-static conditions with daily renewal. This study was reported to follow EPA-821-R-02-014: Method 1006. Five replicates of eight *M. beryllina* were exposed a synthetic seawater control or the test substance prepared as water accommodated fractions (WAFs) at 0.0001, 0.001, 0.01, 0.10 or 0.20 ppt. A

stock solution of 5 g test substance per one thousand milliliters dilution water was prepared in a sealed 2 L glass beaker and mixed for 24 hours on magnetic stirrer using ½" diameter by 3" long stir bar. The depth of the vortex of the mixing stock solution was adjusted to approximately 1/3 the total depth of the solution. After mixing for 24 hours, the stock solution was allowed to settle for 60 minutes. After settling, the test material (WAF) for the stock solution was siphoned from approximately 1.5" below the dilution water surface: the interface of the water soluble and insoluble fraction. An aliquot of this stock solution was diluted with synthetic seawater until a 1.25 ppt stock solution was prepared. This stock solution was used daily to prepare test concentrations. The test temperature was maintained at $25 \pm 1^\circ\text{C}$. Survival and growth of *M. beryllina* larvae exposed to the test substance were not reduced significantly at any concentration tested. The 7-day NOEC and LOEC values were 0.20 ppt WAF and > 0.20 ppt WAF, respectively, for both survival and growth. This is not an acceptable test for several reasons. It is not clear why 0.0002 ppb or 0.2 ppt was the highest concentration tested. Appendixes were not provided with the submission to determine the water chemistry values, dry weight values, summary statistics, preparation of the test concentrations, etc. They are reported to be in the appendixes. It is not possible to accept only part of this data. Ninety six hour EC50 values were not reported within this 7 day study report. Since a 7 day ecotoxicity study is not a chronic study for OCSPP, the LOEC and NOEC were not used for chronic endpoints.

7-day NOEC (survival and growth) = 0.20 ppt WAF
 7-day LOEC (survival and growth) > 0.20 ppt WAF

Aquatic Invertebrates Ectotoxicity Test:

(1) Eurofins Norsk Miljøanalyse AS conducted a 48-hour toxicity test in the marine copepod *Acartia tonsa* with L-14-0050 (purity= 93.4%). The study was reported to follow ISO 14669 (1999). Six replicates of five *A. tonsa* were exposed to a blank control (seawater enriched with nutrients) and four replicates of five *A. tonsa* were exposed to the LVE substance as water accommodated fractions (WAFs) at nominal test concentration of 1.0, 1.8, 3.4, 5.6, 10.0, 18.2 and 31.9 mg/L. Analytical measurements were not conducted. Because the test substance was insoluble in water, WAFs were prepared individually. Appropriate amounts of the test substance were mixed with growth medium, stirred with a spin-bar for 22 hours at a speed which formed a vortex one-third of the depth of the fluid content and allowed to stand for about 1.5 hours. Closed aspirator bottles were used and samples for testing were drawn off through a drain port near the bottom of the bottle. Over the course of the study, water temperature ranged from $18.8 - 20.7^\circ\text{C}$, and dissolved oxygen ranged from 7.0 – 7.4 mg/L. At the start of the study, the initial pH ranged from 8.2 – 8.3. The seawater had a salinity of 34.5 ‰. A loading rate of 200 *A. tonsa*/L was calculated. Percent mortality at 0 (control), 1.0, 1.8, 3.4, 5.6, 10.0, 18.2 and 31.9 mg/L was 0%, 20%, 45%, 75%, 100%, 100%, 100% and 100% at 48 hours, respectively. Complete lethality occurred within an hour at the three highest concentrations; therefore, pH and dissolved oxygen were only recorded once in these test groups. The 48-hour LC50, based on nominal loading rates, was determined to be 1.8 mg a.i./L WAF. This is an acceptable test.

48-hour LC50 = 1.8 mg a.i./L (WAF)

(2) Eurofins Norsk Miljøanalyse AS conducted a 10-day toxicity test in the marine amphipod *Corophium volutator* with L-14-0050 (purity= 93.4%). The study was reported to follow OSPAR Protocols on Methods for the Testing of Chemicals Used in the Offshore Oil Industry, OSPAR Commission 2005, Part A: A Sediment Bioassay Using an Amphipod *Corophium* sp. Three replicates of ten *C. volutator* were exposed to the LVE substance at nominal concentrations of 6.1, 11.0, 18.8 and 40.4 mg/kg sediment dry weight. Additionally, six replicates of ten *C. volutator* were exposed to a blank control (sediment). Sediment (organic content: 3.4%, silt fraction: 73%) was homogenized before preparing the test sediment and each test concentration was prepared by the following procedure. An appropriate amount of test substance was dissolved in approximately 5 mL of acetone and then added to approximately 80 g pre-dried sediment. After the acetone had dried off in a fume cupboard, the sample was then added to approximately 450 g of damp sediment in a plastic bucket. Seawater (130 mL) was then added to the bucket and then the bucket was shaken (120 rpm) for about 5 hours. The sediment was split into three beakers, 400 mL of seawater was added to each, and the buckets were aerated over night in a climate controlled room at 15°C . Ten animals were randomly selected for each beaker. Six glass containers were prepared to serve as blanks. The sediment in the blanks was treated like the test sediment but without adding the test substance. Over the course of the study, temperature ranged from $14.6 - 16.0^\circ\text{C}$, and dissolved oxygen concentration ranged from 89 – 100% saturation. At the start of the test, the initial pH was 8.1. The seawater had a salinity of 34.4 ‰. The % mortality at 0 (control), 6.1,

11.0, 18.8 and 40.4 mg/kg dry weight was 0%, 3%, 37%, 40% and 73%, respectively. The 10-day LC50 was reported to be 20.0 mg a.i./kg sediment dry weight. The 10-day NOEC value was 5.7 mg a.i./kg sediment dry weight. This was an acceptable test.
10-day LC50 = 20.0 mg a.i./kg sediment dry weight
10-day NOEC = 5.7 mg a.i./kg sediment dry weight

(3) Environmental Enterprises USA, Inc. conducted a 7-day survival, growth and fecundity test in mysid (*Mysidopsis bahia*) with L-14-0050 (purity= 93.4%) under semi-static conditions with daily renewal. This study was reported to follow EPA-821-R-02-014: Method 1007. Eight replicates of *M. bahia* were exposed to a dilution water control or the test substance as water accommodated fractions (WAFs) at nominal concentrations of 0.0001, 0.001, 0.01, 0.10 or 0.20 ppt. A stock solution of 5 g test substance per one thousand milliliters dilution water was prepared in a sealed 2 L glass beaker and mixed for 24 hours on magnetic stirrer using ½" diameter by 3" long stir bar. The depth of the vortex of the mixing stock solution was adjusted to approximately 1/3 the total depth of the solution. After mixing for 24 hours, the stock solution was allowed to settle for 60 minutes. After settling, the test material (WAF) for the stock solution was siphoned from approximately 1.5" below the dilution water surface: the interface of the water soluble and insoluble fraction. An aliquot of this stock solution was diluted with synthetic seawater until a 1.25 ppt stock solution was prepared. This stock solution was used daily to prepare test concentrations. The test temperature was maintained at 25 ± 1°C. Survival and growth were not significantly reduced at any concentration tested. Based on nominal concentrations, the NOEC and LOEC values were 0.20 ppt WAF and > 0.20 ppt WAF, respectively, for both survival and growth. This is not an acceptable test for several reasons. It is not clear why 0.0002 ppb or 0.2 ppt was the highest concentration tested. Appendixes A-E were not provided with the submission to determine the water chemistry values, dry weight values, summary statistics, preparation of the test concentrations, etc. They are reported to be in the appendixes. It is not possible to accept only part of this data. Forty eight hour EC50 values were not reported within this 7 day study report. Since a 7 day ecotoxicity study is not a chronic study for OCSPP, the LOEC and NOEC were not used for chronic endpoints.

7-day NOEC (survival and growth) = 0.20 ppt (WAF)

7-day LOEC (survival and growth) > 0.20 ppt (WAF)

Algal Ecotoxicity Test:

Eurofins Norsk Miljøanalyse AS conducted a 72-hour toxicity study in the marine algae *Skeletonema costatum* with L-14-0050 (purity= 93.4%) under static conditions. The study was reported to follow ISO 10253 (2006). *S. costatum* (2500 cells/mL) were exposed to a blank control (seawater enriched with nutrients; six replicates) or the LVE substance (3 replicates) as water accommodated fractions (WAFs) at nominal concentrations of 1.0, 1.8, 3.4, 5.6 and 10 mg/L. The algae were incubated under continuous light (> 50 µE/m²/sec) with constant shaking (110 rpm). Analytical measurements were not conducted. Because the test substance was insoluble in water, WAFs were prepared individually. Appropriate amounts of the test substance were mixed with growth medium, stirred with a spin-bar for 22 hours at a speed which formed a vortex one-third of the depth of the fluid content and allowed to stand for about 1.5 hours. Closed aspirator bottles were used and samples for testing were drawn off through a drain port near the bottom of the bottle. Over the course of testing, temperature ranged from 18.4 – 21.1°C and pH ranged from 7.3 – 8.8. The seawater had a salinity of 34.5 ‰. The cell density in the control group increased by a factor of > 16 within 72 hours. The lowest concentration of 1.0 mg/L WAF resulted in 100% inhibition of growth. Therefore, the 72-hour EL50 is < 1.0 mg/L WAF (lowest concentration tested) and the 72-hour NOEC could not be determined (< 1.0 mg/L WAF). This is not an acceptable study since all organisms at all test concentrations stopped growing before the end of the test. EPA recommends initially to conduct a range finding study prior to future definitive toxicity test concentration determinations.

72-hour EL50 (growth rate) < 1.0 mg/L (WAF)

72-hour NOEL (growth rate) < 1.0 mg/L (WAF)

72-hour LOEL (growth rate) = 1.0 mg/L (WAF)

Resman USA (sponsor) submitted five complete or partially complete ecotoxicity studies on L-14-0050. Two of the five studies were considered acceptable. Due to the sparingly soluble nature of L-14-0050, the testing laboratory conducted WAF testing for four out of five of their ecotoxicity tests. The 48-hour aquatic invertebrate EC50 of 1.8 mg a.i./L is from an acceptable

toxicity study, but will not be used for the purposes of acute or chronic COC determination since the QSAR predicted ecotoxicity endpoint values (E/LC50) for fish and algae result in higher toxicity from L-14-0050. It is important to note that the aquatic invertebrate chronic value for L-14-0050 was estimated to be 0.36 mg/L based on an acute to chronic ratio of 5. Acceptable fish and algal ecotoxicity studies were not provided to EPA for L-14-0050. While the sediment study is considered acceptable, the chronic and acute COCs are currently based on adverse effects in the water column. Therefore, the QSAR predictions will be used to calculate the chronic and acute COCs. The QSAR predicted acute fish, acute Daphnia, and algae L/EC50s for L-14-0050 are 1.3 mg/L, 0.23 mg/L, and 0.29 mg/L, respectively. The predicted chronic values for fish, Daphnia, and algae are 0.26 mg/L, 0.046 mg/L, and 0.22 mg/L, respectively. The acute concentration of concern (COC) for L-14-0050 is 73 ppb (290 ppb / 4 (uncertainty factor)), based on the QSAR 96-hour EC50 for algae. The chronic COC for L-14-0050 is 22 ppb (220 ppb / 10 (uncertainty factor)), based on the QSAR chronic value for algae.

Acute COC = 73 ppb
Chronic COC = 22 ppb

Ecotox Reviewer by J. Gallagher
Date: 12/6/2013

Ecotox Factors:

Assessment Factor:	10
Concern Concentration:	
- Acute Value	
Concern Concentration:	22
- Chronic Value	

V. Summary of Exposures/Releases

Engineering Summary: L-14-0050

Exposures/Releases	Release	Release	Release
Scenario	Use: Tracer Chemical in Oil and Gas Wells	Use: Tracer Chemical in Oil and Gas Wells	Use: Tracer Chemical in Oil and Gas Wells
Sites	124	124	124
Media	Incineration	Deepwell Injection	Water
Descriptor A	Output 2	Output 2	Output 2
Quantity A (kg/site/day)	2.3E-1	5.0E-5	1.4E-6
Frequency A (day/year)	350	350	350
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From	Release to Refinery from Separation Process	Release to Water or Land from On-Shore Separation Process	Release to Water or Land from On-Shore Separation Process
Workers			
Exposure Type			

Engineering Summary: Exposures/Releases	Release	Release	Exposure
Scenario	Use: Tracer Chemical in Oil and Gas Wells	Use: Tracer Chemical in Oil and Gas Wells	Use: Tracer Chemical in Oil and Gas Wells
Sites	124	124	124
Media	Landfill	Water or Landfill	Dermal
Descriptor A	Output 2	Output 2	High End
Quantity A (kg/site/day)	8.3E-6	1.0E-4	1.7E-1
Frequency A (day/year)	350	350	250
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From	Release to Water or Land from On-Shore Separation Process	Equipment and Storage Tank Cleaning	Equipment and Storage Tank Cleaning
Workers			992
Exposure Type			Liquid

V. Summary of Exposures/Releases

Engineering Summary:

Exposures/Releases			
Scenario			
Sites			
Media			
Descriptor A			
Quantity A (kg/site/day)			
Frequency A (day/year)			
Descriptor B			
Quantity B (kg/site/day)			
Frequency B (day/year)			
From			
Workers			
Exposure Type			

VI. Focus Decision and Rationale

Regulatory Actions

Regulatory Decision: LVE Grant

Decision Date: 12/09/2013

Type of Decision:

Rationale: L-14-0050 was granted. Human health hazard concerns were low-moderate for dermal and inhalation exposures. Potential risks to workers were mitigated by negligible exposures. Ecotoxicity hazard concerns were moderate based on submitted test data. Potential risks to the environment were low due to no exceedances of the COC during the release period. This LVE was not bound at 60 kg/yr and was assessed at 10,000 kg/yr. This LVE is used as a tracer in fracking.

COC: Chronic – 5 ppb, Acute – 73 ppb

Summary of Exposures and Releases

Proc

9 sites, 250 days/yr, 0 workers

Inhalation: Not Expected

Dermal: Non-Quantifiable

Use

124 sites, 350 days/yr, 992 workers

Inhalation: Negligible (VP < 0.001 torr)

Dermal: 1.7E-1 mg/day (0.02% Liquid)

Releases to Water: 1.4E-6 kg/site-day over 350 days/yr

Releases to Water: 1.0E-4 kg/site-day over 350 days/yr

Or Landfill

Releases via Incineration: 2.3E-1 kg/site-day over 350 days/yr

Releases via Landfill: 8.3E-6 kg/site-day over 350 days/yr

Releases to Deepwell Injection: 5.0E-5 kg/site-day over 350 days/yr

Fate Releases to Water (0% Removal)

SWC: 9.53E-02 ppb

DW: LADD: 6.83E-08 mg/kg/day, ADR: 4.35E-06 mg/kg/day

FI: LADD: 5.06E-09 mg/kg/day, ADR: 2.83E-07 mg/kg/day

P2 Rec Comments:

Testing:

Final Recommended:

Health:

Eco:

Fate:

Other:

SAT Report

PMN Number: **L-14-0050**

SAT Date: **12/3/2013**

Print Date: **11/17/2015**

Related cases:

Health related cases:

Ecotox related cases:

Concern levels:

Type of Concern:	<u>Health</u>	<u>Eco</u>	<u>Comments</u>
Level of Concern:	1-2	2	

<u>Persistence</u>	<u>Bioaccum</u>	<u>Toxicity</u>	<u>Comments</u>
3	1	1	
		Awaiting	
		Human Health	
		Entry	
		Awaiting	
		Human Health	
		Entry	
		Awaiting	
		Human Health	
		Entry	

Exposure Based Review:

Health: No

Ecotox: No

Routes of exposure:

Health: Dermal Drinking Water Inhalation

Ecotox: All releases to water

Fate: ;

Keywords:

Keywords:

Summary of Assessment:

Fate:

Fate Summary: L-14- -50

FATE: Estimations for typical MW 651

Liquid with MP < 25 C (E)

log Kow = 3.64 (E)

S = 9.31 mg/L at 25 C (E)

VP < 1.0E-6 torr at 25 C (E)

BP > 400 C (E)

H < 1.00E-8 (E)

log Koc = 6.69 (E)

log Fish BCF = 2.07 (E)

log Fish BAF = 2.27 (E)

POTW removal (%) = 0-25 via sorption; [REDACTED]

[REDACTED] L-14-0050: OECD 306(Biodeg in Seawater, Closed Btl): <4%/28d.

Time for complete ultimate aerobic biodeg > mo

Sorption to soils/sediments = moderate

PBT Potential: P3B1

*CEB FATE: Migration to ground water = moderate

Health:

Health Summary: Absorption of the low molecular weight fraction (100% < 1000, 0% < 500) is poor all routes, based on physical/chemical properties. There are concerns for solvent irritation to the eye, skin, and mucous membranes and for solvent neurotoxicity.

Ecotox:

Test Organism	Test Type	Test End Point	Predicted	Measured	Comments
fish	96-h	LC50	1.3		
daphnid	48-h	LC50	0.23	1.8	WAF
green algal	96-h	EC50	0.29		
fish	–	chronic value	0.26		ACR 5
daphnid	–	chronic value	0.046	0.36	WAF; ACR 5
algal	–	chronic value	0.22		
Sewage Sludge	3-h	EC50	–		
Sewage Sludge	–	Chronic Value	–		

Ecotox Values Comments: Predictions are based on SARs for nonionic surfactants; SAR chemical class = surfactant-nonionic [REDACTED]; MW 732 with 100% < 1000 and 0% < 500; S = 0.12 mg/L @ 20 C (P); liquid with unknown mp (P); pH7; effective concentrations based on 100% active ingredients and mean measured concentrations; DW hardness <150.0 mg/L as CaCO₃; and DW TOC <2.0 mg/L;

Ecotoxicity Test Data Results: L-14-0050; [REDACTED]

Fish Ecotoxicity Test:

Environmental Enterprises USA, Inc. conducted a 7-day larval survival and growth test in the inland silverside (*Menidia beryllina*) with L-14-0050 (purity= 93.4%) under semi-static conditions with daily renewal. This study was reported to follow EPA-821-R-02-014: Method 1006. Five replicates of eight *M. beryllina* were exposed a synthetic seawater control or the test substance prepared as water accommodated fractions (WAFs) at 0.0001, 0.001, 0.01, 0.10 or 0.20 ppt. A stock solution of 5 g test substance per one thousand milliliters dilution water was prepared in a sealed 2 L glass beaker and mixed for 24 hours on magnetic stirrer using ½” diameter by 3” long stir bar. The depth of the vortex of the mixing stock solution was adjusted to approximately 1/3 the total depth of the solution. After mixing for 24 hours, the stock solution was allowed to settle for 60 minutes. After settling, the test material (WAF) for the stock solution was siphoned from approximately 1.5” below the dilution water surface: the interface of the water soluble and insoluble fraction. An aliquot of this stock solution was diluted with synthetic seawater until a 1.25 ppt stock solution was prepared. This stock solution was used daily to prepare test concentrations. The test temperature was maintained at $25 \pm 1^\circ\text{C}$. Survival and growth of *M. beryllina* larvae exposed to the test substance were not reduced significantly at any concentration tested. The 7-day NOEC and LOEC values were 0.20 ppt WAF and > 0.20 ppt WAF, respectively, for both survival and growth. This is not an acceptable test for several reasons. It is not clear why 0.0002 ppb or 0.2 ppt was the highest concentration tested. Appendixes were not provided with the submission to determine the water chemistry values, dry weight values, summary statistics, preparation of the test concentrations, etc. They are reported to be in the appendixes. It is not possible to accept only part of this data. Ninety six hour EC50 values were not reported within this 7 day study report. Since a 7 day ecotoxicity study is not a chronic study for OCSPP, the LOEC and NOEC were not used for chronic endpoints.

7-day NOEC (survival and growth) = 0.20 ppt WAF

7-day LOEC (survival and growth) > 0.20 ppt WAF

Aquatic Invertebrates Ectotoxicity Test:

(1) Eurofins Norsk Miljøanalyse AS conducted a 48-hour toxicity test in the marine copepod *Acartia tonsa* with L-14-0050 (purity= 93.4%). The study was reported to follow ISO 14669 (1999). Six replicates of five *A. tonsa* were exposed to a blank control (seawater enriched with nutrients) and four replicates of five *A. tonsa* were exposed to the LVE substance as water accommodated fractions (WAFs) at nominal test concentration of 1.0, 1.8, 3.4, 5.6, 10.0, 18.2 and 31.9 mg/L. Analytical measurements were not conducted. Because the test substance was insoluble in water, WAFs were prepared individually. Appropriate amounts of the test substance were mixed with growth medium, stirred with a spin-bar for 22 hours at a speed which formed a vortex one-third of the depth of the fluid content and allowed to stand for about 1.5 hours. Closed aspirator bottles were used and samples for testing were drawn off through a drain port near the bottom of the bottle. Over the course of the study, water temperature ranged from 18.8 – 20.7°C, and dissolved oxygen ranged from 7.0 – 7.4 mg/L. At the start of the study, the initial pH ranged from 8.2 – 8.3. The seawater had a salinity of 34.5 ‰. A loading rate of 200 *A. tonsa*/L was calculated. Percent mortality at 0 (control), 1.0, 1.8, 3.4, 5.6, 10.0, 18.2 and 31.9 mg/L was 0%, 20%, 45%, 75%, 100%, 100%, 100% and 100% at 48 hours, respectively. Complete lethality occurred within an hour at the three highest concentrations; therefore, pH and dissolved oxygen were only recorded once in these test groups. The 48-hour LC50, based on

nominal loading rates, was determined to be 1.8 mg a.i./L WAF. This is an acceptable test.
48-hour LC50 = 1.8 mg a.i./L (WAF)

(2) Eurofins Norsk Miljøanalyse AS conducted a 10-day toxicity test in the marine amphipod *Corophium volutator* with L-14-0050 (purity= 93.4%). The study was reported to follow OSPAR Protocols on Methods for the Testing of Chemicals Used in the Offshore Oil Industry, OSPAR Commission 2005, Part A: A Sediment Bioassay Using an Amphipod *Corophium* sp. Three replicates of ten *C.volutator* were exposed to the LVE substance at nominal concentrations of 6.1, 11.0, 18.8 and 40.4 mg/kg sediment dry weight. Additionally, six replicates of ten *C.volutator* were exposed to a blank control (sediment). Sediment (organic content: 3.4%, silt fraction: 73%) was homogenized before preparing the test sediment and each test concentration was prepared by the following procedure. An appropriate amount of test substance was dissolved in approximately 5 mL of acetone and then added to approximately 80 g pre-dried sediment. After the acetone had dried off in a fume cupboard, the sample was then added to approximately 450 g of damp sediment in a plastic bucket. Seawater (130 mL) was then added to the bucket and then the bucket was shaken (120 rpm) for about 5 hours. The sediment was split into three beakers, 400 mL of seawater was added to each, and the buckets were aerated over night in a climate controlled room at 15°C. Ten animals were randomly selected for each beaker. Six glass containers were prepared to serve as blanks. The sediment in the blanks was treated like the test sediment but without adding the test substance. Over the course of the study, temperature ranged from 14.6 – 16.0°C, and dissolved oxygen concentration ranged from 89 – 100% saturation. At the start of the test, the initial pH was 8.1. The seawater had a salinity of 34.4 ‰. The % mortality at 0 (control), 6.1, 11.0, 18.8 and 40.4 mg/kg dry weight was 0%, 3%, 37%, 40% and 73%, respectively. The 10-day LC50 was reported to be 20.0 mg a.i./kg sediment dry weight. The 10-day NOEC value was 5.7 mg a.i./kg sediment dry weight. This was an acceptable test.

10-day LC50 = 20.0 mg a.i./kg sediment dry weight

10-day NOEC = 5.7 mg a.i./kg sediment dry weight

(3) Environmental Enterprises USA, Inc. conducted a 7-day survival, growth and fecundity test in mysid (*Mysidopsis bahia*) with L-14-0050 (purity= 93.4%) under semi-static conditions with daily renewal. This study was reported to follow EPA-821-R-02-014: Method 1007. Eight replicates of *M. bahia* were exposed to a dilution water control or the test substance as water accommodated fractions (WAFs) at nominal concentrations of 0.0001, 0.001, 0.01, 0.10 or 0.20 ppt. A stock solution of 5 g test substance per one thousand milliliters dilution water was prepared in a sealed 2 L glass beaker and mixed for 24 hours on magnetic stirrer using ½” diameter by 3” long stir bar. The depth of the vortex of the mixing stock solution was adjusted to approximately 1/3 the total depth of the solution. After mixing for 24 hours, the stock solution was allowed to settle for 60 minutes. After settling, the test material (WAF) for the stock solution was siphoned from approximately 1.5” below the dilution water surface: the interface of the water soluble and insoluble fraction. An aliquot of this stock solution was diluted with synthetic seawater until a 1.25 ppt stock solution was prepared. This stock solution was used daily to prepare test concentrations. The test temperature was maintained at 25 ± 1°C. Survival and growth were not significantly reduced at any concentration tested. Based on nominal concentrations, the NOEC and LOEC values were 0.20 ppt WAF and > 0.20 ppt WAF, respectively, for both survival and growth. This is not an acceptable test for several reasons. It

is not clear why 0.0002 ppb or 0.2 ppt was the highest concentration tested. Appendixes A-E were not provided with the submission to determine the water chemistry values, dry weight values, summary statistics, preparation of the test concentrations, etc. They are reported to be in the appendixes. It is not possible to accept only part of this data. Forty eight hour EC50 values were not reported within this 7 day study report. Since a 7 day ecotoxicity study is not a chronic study for OCSPP, the LOEC and NOEC were not used for chronic endpoints.

7-day NOEC (survival and growth) = 0.20 ppt (WAF)

7-day LOEC (survival and growth) > 0.20 ppt (WAF)

Algal Ecotoxicity Test:

Eurofins Norsk Miljøanalyse AS conducted a 72-hour toxicity study in the marine algae *Skeletonema costatum* with L-14-0050 (purity= 93.4%) under static conditions. The study was reported to follow ISO 10253 (2006). *S. costatum* (2500 cells/mL) were exposed to a blank control (seawater enriched with nutrients; six replicates) or the LVE substance (3 replicates) as water accommodated fractions (WAFs) at nominal concentrations of 1.0, 1.8, 3.4, 5.6 and 10 mg/L. The algae were incubated under continuous light (> 50 $\mu\text{E}/\text{m}^2/\text{sec}$) with constant shaking (110 rpm). Analytical measurements were not conducted. Because the test substance was insoluble in water, WAFs were prepared individually. Appropriate amounts of the test substance were mixed with growth medium, stirred with a spin-bar for 22 hours at a speed which formed a vortex one-third of the depth of the fluid content and allowed to stand for about 1.5 hours.

Closed aspirator bottles were used and samples for testing were drawn off through a drain port near the bottom of the bottle. Over the course of testing, temperature ranged from 18.4 – 21.1°C and pH ranged from 7.3 – 8.8. The seawater had a salinity of 34.5 ‰. The cell density in the control group increased by a factor of > 16 within 72 hours. The lowest concentration of 1.0 mg/L WAF resulted in 100% inhibition of growth. Therefore, the 72-hour EL50 is < 1.0 mg/L WAF (lowest concentration tested) and the 72-hour NOEC could not be determined (< 1.0 mg/L WAF). This is not an acceptable study since all organisms at all test concentrations stopped growing before the end of the test. EPA recommends initially to conduct a range finding study prior to future definitive toxicity test concentration determinations.

72-hour EL50 (growth rate) < 1.0 mg/L (WAF)

72-hour NOEL (growth rate) < 1.0 mg/L (WAF)

72-hour LOEL (growth rate) = 1.0 mg/L (WAF)

Resman USA (sponsor) submitted five complete or partially complete ecotoxicity studies on L-14-0050. Two of the five studies were considered acceptable. Due to the sparingly soluble nature of L-14-0050, the testing laboratory conducted WAF testing for four out of five of their ecotoxicity tests. The 48-hour aquatic invertebrate EC50 of 1.8 mg a.i./L is from an acceptable toxicity study, but will not be used for the purposes of acute or chronic COC determination since the QSAR predicted ecotoxicity endpoint values (E/LC50) for fish and algae result in higher toxicity from L-14-0050. It is important to note that the aquatic invertebrate chronic value for L-14-0050 was estimated to be 0.36 mg/L based on an acute to chronic ratio of 5. Acceptable fish and algal ecotoxicity studies were not provided to EPA for L-14-0050. While the sediment study is considered acceptable, the chronic and acute COCs are currently based on adverse effects in the water column. Therefore, the QSAR predictions will be used to calculate the chronic and acute COCs. The QSAR predicted acute fish, acute Daphnia, and algae L/EC50s for

L-14-0050 are 1.3 mg/L, 0.23 mg/L, and 0.29 mg/L, respectively. The predicted chronic values for fish, Daphnia, and algae are 0.26 mg/L, 0.046 mg/L, and 0.22 mg/L, respectively. The acute concentration of concern (COC) for L-14-0050 is 73 ppb (290 ppb / 4 (uncertainty factor)), based on the QSAR 96-hour EC50 for algae. The chronic COC for L-14-0050 is 22 ppb (220 ppb / 10 (uncertainty factor)), based on the QSAR chronic value for algae.

Acute COC = 73 ppb
Chronic COC = 22 ppb

Ecotox Reviewer by J. Gallagher
Date: 12/6/2013

Factors	Values	Comments
Assessment Factor	10	
Concentration of Concern (ppb) Acute		
Concentration of Concern (ppb) Chronic	22	
SARs	nonionic surfactants	
SAR Class	surfactant-nonionic- [REDACTED]	
TSCA New Chemical Category	Nonionic Surfactants	

Ecotox Factors Comments:

SAT Chair: J. Kwiat, 564-7653

Fate assessor: **Ecotox assessor:** **Health assessor:**